Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: BiDil® Oral Disintegrating Tablets Clinical Edit
Date: August 24, 2006
Prepared for:
Prepared by: Missouri Medicaid

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of BiDil© (isosorbide dinitrate 20mg/hydralazine HCl 37.5mg tablets).

Why was this Issue Selected: BiDil® is a branded drug product containing isosorbide dinitrate and hydralazine hydrochloride in a fixed-dose combination tablet. Isosorbide dinitrate is a vasodilator with effects on both arteries and veins, while hydralazine hydrochloride predominantly works as an arterial vasodilator. BiDil® is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, prolong time to hospitalization for heart failure, and to improve patient-reported functional status. Standard therapy generally includes a loop diuretic, ACE inhibitor or ARB, along with a beta blocker. Many patients also receive a cardiac glycoside or an aldosterone antagonist. Bidil® contains 20mg of isosorbide dinitrate and 37.5mg hydralazine hydrochloride. Generic forms of each are individually available in oral tablets at significant lower costs of therapy. The fixed-dose combination dosage form is roughly 4 times more expensive than the MAC'd oral generic products.

Program-specific information:

Drug	Dosage Form	Cost per Dosage Form
• BiDil®	*20mg/37.5mg tab*	*$1.80WAC*

Setting & Population: All patients.

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**
☒ **Appropriate Indications** ☐

Data Sources:	☐ Only administrative databases	☒ Databases + Prescriber-supplied

Setting & Population

- Drug for review: BiDil® (isosorbide dinitrate 20mg/hydralazine HCl 37.5mg tablets)
- Age range: All ages
- Gender: Male and female

Approval Criteria

- Patient race = African American
- Trial and failure of each individual generic active ingredients in the past 45 days.
- Documented ADE/ADR to individual generic products.

Denial Criteria

- Failure to meet approval criteria.

References

1. Facts and Comparisons, p.451 – 466h. 2005.
2. USPDI, Micromedex, 2005.
3. NitroMed, Inc., AMCP Formulary Submission Dossier - BiDil®, Lexington, MA 02421. August 2005.